Harbin Medical University

Institutional Research Board Report

No.: HMUIRB20170009

The research on **Procalcitionin as diagnosis marker to distinguish upper and lower gastrointestinal perforation is intended to be carried out by Dr. Yang Gao of** department of Critical Care Medicine, the Second Affiliated Hospital of Harbin Medical University. The present study is a retrospective cohort study. Ethical board approval from the Human Ethics Review Board, Harbin Medical University is on the process.

1.Program Information

1)Research project title: Procalcitionin as diagnosis marker to distinguish upper and lower gastrointestinal perforation

2)**Undertaking project enterprises:** Department of Critical Care Medicine, the Second Affiliated Hospital of Harbin Medical University

3)**Project leader: Kaijiang Yu; Position: Chief physician**

4)**Dates of the program: From 1/2013 to 12/2016**

2.Chief Content of study

ABSTRACT

Background: This study aimed to assess accuracy and efficacy of Procalcitionin (PCT) as diagnosis marker in verifying upper and lower GIP.

Methodology/Principal Findings: This retrospective study included 46 patients from SICU ward of the Second Affiliated Hospital of Harbin Medical University who were confirmed to be with GIP between June 2013 and December 2016. Patients were divided into upper (n = 19) and lower (n = 27) GIP groups according to perforation site above or below Treitz ligament. PCT and WBC count were obtained before laparotomy and then compared between groups. Meanwhile diagnosis effect of PCT was analyzed. Patients with lower GIP exhibited significantly higher APACHE II score, SOFA score and serum PCT level than patients with upper GIP (P=0.017, 0.004, 0.001,respectively). There was a significant positive correlation between serum PCT level and APACHE II score, SOFA score (correlation coefficients were r=0.715 and r=0.611, respectively), while there was a significant negative correlation between serum PCT level and Prognosis (correlation coefficients was r=-0.414). WBC count was not significantly different between groups, and WBC count had no significant correlation with serum PCT level, APACHE II score, SOFA score and Prognosis. The area under the curve of PCT predictive value to distinguish upper or lower GIPs was 0.778. Patients with serum PCT level above 17.94 ng/dl had a high likelihood of lower GIP, which sensitivity and specificity were 100% and 42.1%, respectively.

Conclusions/Significance: Serum PCT level was a reliable and accurate diagnosis marker in identifying upper or lower GIPs before laparotomy.

Key Words: Procalcitionin; white blood cell count ; gastrointestinal perforation; sepsis; APACHE II score; SOFA score

3.**Review evaluation opinions**

Safety and fairness principle has been fully considered in the experiments plans. All of the volunteers gave written informed consent, and the content of the research have no harm or risk. Before the research was conducted, ethical board approval from the Harbin Medical University was obtained. No conflict of interest exists in this study.

4.**Conclusion**

The rights and interests of volunteer subjects have been adequately protected in the study, and there is no potential risk to the volunteers. Agree to the study work as planned.

Institutional Research Board of Harbin Medical University

04/17/2017